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September 24, 2013

Andy Vickery
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RE: Humira and Skin Cancer

Dear Mr. Vickery:

At your request, the following is a summary of my opinions regarding the increased risk for development of non-melanoma skin cancer in patients who receive Humira. For the reasons which follow, it is my opinion that based on the available literature as well as Abbott's own internal clinical trial data and email correspondence, there is a causal association between Humira and squamous cell carcinoma ["SCC"] like that suffered by Cynthia DiBartolo. Moreover, internal Abbott data reflects that the average time of exposure for patients on Humira that contracted SCC was nearly identical to the period of Ms. DiBartolo's use.

I do not keep a list of the cases that I have testified on. However, I was able to find a copy of what I provided in an earlier letter regarding an Abbott case and I will reprint that list below. In addition, I will list other cases that I can recall that are more recent.

Barber vs. DHEW
Bean-Jensen vs. Beazer Homes
Bravo vs. DHHS
Calisi vs. Abbott
Cary vs. State Farm
Chitwood vs. Atkinson
Cochrane vs. DHEW
Crane vs. Open Door, Inc.
Engleman vs. Watsonville Community Hospital
Fields vs. DHEW
Goosen vs. Nitro, Inc.
Lamp vs. Lichtenstein
Lawyer vs. The War Memorial
Madriz vs. Solano School District
Mahon vs. Carpenter
Marquez vs. Gordon Sand

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Mitchell vs. Stevenson
Murthy vs. Abbott
Neifer vs. Zevallos
Olivera vs. Avila
Oddo vs. Certainty Corporation
Parsons vs. DHHS
Phillips vs. Wood
Prestera vs. Cleveland Clinic
Ramsay vs. DHHS
Ray vs. Allergan
Raymond vs. Sidek
Rydberg vs. DHHS
Shaddox vs. MacCarther
Smith vs. HBS
Tietz vs. Abbott
Walters vs. Volpi
Warnock vs. Glodek
Warren vs. Union Carbide
Weaver vs. Huelskoetter

First, the relationship between the use of Humira and the development of non-melanoma skin cancer ["NMSC"] is directly related to our understanding of the phylogeny, ontogeny and function of the immune system. The immune system was developed in biologic evolution to fight infections, i.e. combat agents in the outside world that are potentially invasive. The immune system is found throughout all tissues and organs in the body and indeed evidence of an immune system can be found in the most primitive forms of life, emphasizing its importance. More importantly, comparative evolution and studies of the immunobiology of organisms as diverse as earthworms to people reveal common themes, the most significant of which is the absolute necessity for an adequate immune system to protect us from the outside world. This concept of protection extends to not only infectious agents, but also to the appearance of certain malignancies. In fact, as with any other genetically determined system in the body, there are large numbers of genetic flaws or deficiencies that exist either naturally or are experimentally inducible. For example, there is long and established literature regarding the risks of cancer in human children born with immune deficiencies, such that "the immune system plays an important role in the regulation and outcome of cancer has been an intriguing concept for almost a century" (1). The majority of attention on children with immune deficiency has focused on hematologic malignancies, particularly lymphoma (2). Primary immune deficiency is relatively uncommon and the number of patients who suffer from a specific primary immune deficiency is, of course, even less. However, such children illustrate the importance of the immune system and the relationship between immunity and neoplasia. Such observations have helped form the basis of the immune mechanisms that protect against cancer (3-5). This data has collectively resulted in our understanding of the immune system involving three separate phases of cancer biology, coined elimination,

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equilibrium and escape (4). In the elimination component, which is strikingly similar to "immunosurveillance," the immune system's function is to eliminate the cancer. Comparative studies show similar results in experimental systems in which mice, have a specific immune associated gene deleted, and in turn, subsequently development high incidence of cancer as well as increased evidence of infectious disease. In fact, individual immune effector pathways specifically influence the risks of specific cancers (6-10). Of the 150 different primary immune deficiencies, there is evidence that specific cancers can be associated with specific immune issues (11-16). In short, a functioning immune system plays a critical role not only in fighting infections, but also in immunosurveillance against tumors.

Pleiotropy occurs when one gene influences a multitude of phenotypic traits. In other words, one gene may have an effect on a large number of characteristics or traits of a particular organism. The human immune system is extraordinarily pleiotropic in nature because it is designed not only to recognize and defend the body against a large variety of infectious agents that a host may face over the course of its life, but it also must cope and handle specific local microenvironmental influences within tissues. This is exemplified by the skin and the unique cutaneous immune system. The dermal immune system is similar to the systemic immune system in having both innate and adaptive mechanisms. The skin contains specialized antigen presenting cells and also a unique population of T cells that bear homing receptors. Further, activated keratinocytes secrete cytokines, chemokines and also express a variety of co-stimulatory molecules (17-19). For example, the immune system in the human gut, while sharing many principles with the skin, has its own unique group or repertoire of biologic machinery. This is true of virtually every organ in the body (20). In fact, defects in any particular organ's specific biology can result in cancer development in that site without necessarily carrying over to another site. One relevant example of this would include ultraviolet light induced cancer in the skin, tobacco associated cancers in the lung, as well as a whole variety of data on chemically induced autoimmunity, i.e. a form of dysregulation of this intricate repertoire of immune cells (17, 21).

Any discussion of non-melanoma skin cancer must include the adverse effects of ultraviolet radiation, as it is considered the primary cause of NMSC (22). In fact, it is well known that UV radiation produces immunosuppression and by suppressing cell mediated immune reactions, this contributes to the development of skin cancer (23). These latter observations of depressed immunity and skin cancer were described as early as 1980 (24). The immunological basis is clearly multi-factorial but, in 1994, cytokines, including TNF-α, were implicated in the events that occur (25, 26). More recent data indicate that TNF-α induced apoptosis is a key cancer defense strategy and that interference with this mechanism can influence squamous cell carcinomas that are induced by papilloma virus (27). The TNFR-associated death domain protein has been described to play a key role in what has been coined a pro-survival complex I formation (28). Clearly, the modulation of TNF has biologic potential and it is likely different in specific individuals based on their own genetic predisposition; this again is highlighted by specific defective cell mediated responses in specific genetic polymorphisms of people (29-31). Indeed, the individual genetic susceptibility is part and parcel of differences found within epidemiologic associations and likely explains variances between studies. In the case of non-melanoma skin cancers, these data are well exemplified by the

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pathogenesis of such lesions in organ transplant recipients (32). Finally, it should be noted that one can transfer immune suppression from ultraviolet irradiated mice to normal mice using CD4 cells (33, 34).

Although the immune system and its functions have been discussed for more than 100 years, clearly our knowledge has become more intricate with advances in molecular biology. On the other hand, as cited below, our data, including proof of principle, epidemiologic analysis, and animal studies, all contain key features that fulfill Bradford-Hill criteria for causation and illustrate the essential role of a healthy, intact immune system in tumor surveillance and development. Sir Bradford-Hill's criteria for causation is an analytical framework for determining causal relationships and is premised upon nine separate factors or criteria (35). Generally speaking, the Bradford-Hill criteria consists of the following:

(1) Strength of the association;
(2) Consistency;
(3) Specificity of the association;
(4) Temporality;
(5) Biological gradient or dose-response relationship;
(6) Biologic plausibility;
(7) Coherence;
(8) Experiment ("dechallenge" or "rechallenge"); and
(9) Analogy.

The principles of cell mediated immunity and how it interacts with inflammation in the immune response has been defined in a broad sense for nearly 50 years. Anti-TNF agents, including Humira, are drugs which block a specific cytokine, TNFα, and the observation that cytokines are intricately involved in an adequate immune response was illustrated in a Parke-Davis Award Lecture as early as 1977 (36). At that time it was emphasized that cytokines exert profound influences on inflammatory cell metabolism, cell surface properties, patterns of cell migration and the activation of cells for various biologic activities involved in host defense. Even in 1977, the relationship between cytokines and cancer was noted in patients with some forms of cancer (36).

The appearance of cancer in patients with immune deficiencies has also been described and known for nearly 50 years (24, 37). Although the mechanisms involved are highly dependent on the nature of the immune deficiency and the age of the patients, it is clear and generally accepted within the field of immunology that immunosuppression is associated with the development of cancer (38). More specifically, it is generally understood and accepted within the practice of medicine that immunosuppressive medications are a risk factor for SCC in the head and neck (39).

Essentially, immunodeficiencies are either acquired or inherited syndromes that not only lead, as one would expect, to increased risk of infections and autoimmunity, but neoplasia as well (2). This discussion includes not only specific components of immunity, but also the role of the environment and that of immune

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regulation (40, 41). This is important because TNF-α is a very promiscuous cytokine and, as illustrated below, in terms of its relationships with lymphoid subpopulations, has pleiotropic effects, it will have a more global influence than a selective terminal event in an effector immune response.

In fact, this is especially the case of altered, dysregulated or defective cell mediated immune systems (42). The majority of such cancers are lymphoma and the prognosis in such patients is grave. However, the concept of skin cancer and immune suppression goes far beyond that of congenital immune deficiency syndromes. First, our understanding of the skin includes an immune system which has a repertoire of cell types that are found in virtually every lymphoid organ in the body, including tonsils, lymph node and spleen. Within the skin, there is a rich repertoire of cells which have antigen presenting properties, which serve as a true peripheral organ. These cells have the ability to be involved not only in primary immune protection, but also in secondary immune protection. These cells also include innate immune responses as well as the ability for adaptive responses and, in fact, any immunosuppressive therapy, whether pharmacologic or induced by artificial sources such as ultraviolet light, has the ability to reduce immune function. In addition, with the understanding that some cancers may be induced by viral infections, the risk of developing such tumors in immune-suppressed agents is explicably based on the reduction in cell mediated immune responses against infectious agents (43).

There are several other examples of immunosuppressed conditions which lead to an increased incidence of skin cancer. For example, squamous cell and basal cell carcinomas have been reported to account for 90% of all skin cancers in transplant recipients (44-48). In addition, the incidence of these skin cancers is directly related to the duration of immunosuppressive therapy (44, 47, 49). These data, which include peer review literature, as early as 1990, reflect both the coherence and consistency criteria of Bradford-Hill.

Indeed, in one study in Australia, the incidence of skin cancer was noted to be 7% after one year of immunosuppressive therapy, but 82% cumulative incidence after 20 years (44, 50). This observation was recapitulated in a study in Holland and also is true of basal cell carcinomas (45). Clearly, there is evidence of dose response with respect to immunosuppression and NMSC. Such evidence is indicative of causality under Bradford-Hill.

An additional piece of evidence that further emphasizes the relationship of immunosuppression to skin cancer are data that indicate that a reduction in both dose and use of immunosuppression reduces the risk of skin cancer. In fact, guidelines have been proposed that provide for a gradual reduction in immunosuppressive therapy and a resultant reduction in subsequent development of skin cancer (51). Within the context of these skin cancers and my opinions, I will not specifically opine on the etiological agents that induce skin cancer other than the discussion above on ultraviolet light and papilloma viruses. For completeness, however, it should be noted that those agents that have been associated with skin cancers are specific factors that lead to inflammatory responses in the skin such as ultraviolet light, changes in aging and viral infections (52-56).

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This latter statement is an additional component of Bradford-Hill causation. Agents that inhibit TNFα, including Humira, influence these same inflammatory responses (57). In fact, by further example, it is well known that patients with HIV infections and corresponding immune deficiency also have a significant increase in non-melanoma skin cancer (58). Indeed, this point is an additional Bradford-Hill factor that yet further illustrates the causal relationship of immunocompromised patients with subsequent development of cancer (37, 44, 45, 47, 59-63). It should be noted that the latter include extensive case control studies. Indeed, the mechanisms of action and the biologic plausibility of how drugs which modulate immune systems lead to skin cancer and indeed other carcinomas, are also well established in the literature and data from the Food and Drug Administration. Please see, for example, Table 1, which includes drugs used to treat psoriasis and rheumatoid arthritis in a manuscript by Weaver from the Division of Drug Safety Research of FDA (64). Indeed, the causative agents highlighted therein include specific molecular defects, again illustrating biologic plausibility, a key component of the Bradford-Hill criteria (65).

The evidence that use of anti-TNF agents is associated with immune suppression is well accepted in the peer reviewed medical literature and is consistent with the very purpose by which anti-TNF agents were developed to treat patients with autoimmune disease. The clinical data, including the basic immunological medicine, has been described in multiple publications, including recent literature from my group (57). This evidence of immune suppression has led to increased vigilance for a variety of infectious diseases. For example, data from the British Society for Rheumatology Biologics Register (BSRBR) indicate that the overall risk of serious infections (requiring hospitalization or intravenous antibiotics or resulting in death) was not increased in RA patients treated with TNF antagonists compared to patients treated with conventional DMARDs (66). However, RA patients undergoing anti-TNF therapy were significantly more likely to develop serious infections of the skin and soft tissue; and *Mycobacterium tuberculosis* and other intracellular infections were exclusively observed during anti-TNF treatment. This is consistent with data from spontaneous pharmacovigilance and active surveillance indicating that blockade of TNFα increases the risk not only of tuberculosis, but also of other infectious granulomatous diseases, such as histoplasmosis, cryptococcosis, coccidioidomycosis, listeriosis and aspergillosis (67). This effect does not appear to depend on the underlying disease since it has been observed in patients with RA, AS, PsA and psoriasis, and CD. However, most of the available data concern patients with RA.

In order to understand the pleiotropic and promiscuous nature of blocking the TNF pathway, it is important to discuss the specific effects of anti-TNF on infectious disease since an intact immune system is essential for immune protection against microbes. In most studies, the risk of tuberculosis is already 2- to 4-fold higher in biologic-naïve RA patients compared to healthy controls, but is further increased by a factor of 4–10 in patients treated with TNF antagonists (68-70). Of note, the disease pattern in patients undergoing anti-TNF therapy is highly unusual and resembles that seen in immunocompromised patients. It is characterized by a very high rate of extrapulmonary (56–62%) and disseminated disease (24–28%) (70, 71).

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In contrast, only ~18% of tuberculosis cases in non-immunosuppressed patients manifest as extrapulmonary disease, and disseminated disease occurs in <2% of cases.

It has long been suspected and has been confirmed in recent studies from the U.S., Sweden, France, and the UK that the monoclonal anti-TNF agents infliximab and adalimumab are associated with a markedly higher risk of tuberculosis compared to etanercept, the highest risk being associated with adalimumab (67, 68, 70, 72). Infliximab was also associated with at least a 2-fold higher risk of histoplasmosis, listeriosis and coccidioidomycosis, though not of other granulomatous infections (67). Furthermore, cases of tuberculosis are observed at a relatively constant rate throughout treatment with etanercept, whereas the rate of infection in patients undergoing treatment with infliximab is highest within the first few months after initiation of therapy (70, 71, 73). This suggests that many cases of tuberculosis during infliximab therapy represent reactivation of latent disease, whereas cases occurring during etanercept therapy are more likely to be newly acquired disease. Once the increased risk of tuberculosis during anti-TNF therapy became fully appreciated, rheumatological guidelines began to recommend screening for tuberculosis and to advise prophylactic treatment before initiation of treatment with biologic agents in patients with latent tuberculosis. This has resulted in a marked decrease in the incidence of active tuberculosis in patients treated with TNF antagonists in recent years. However, data from a French registry indicate that a majority of cases occurred in patients with negative screening results, suggesting either inadequate screening or the acquisition of new infections rather than reactivation of latent infection (72). These data illustrate, as above, pleiotropic influences of blocking TNF.

TNFα additionally plays a crucial role in the defense against intracellular bacteria (74, 75). In vitro data suggest that TNFα regulates the expression of TLR-4 in dendritic cells (DCs) (76). TLR-4 is a pattern recognition receptor that plays a central role in the recognition of *M. tuberculosis* and other micro-organisms causing granulomatous infections. In addition, there is ample evidence that TNFα is a key player in the early non-specific immune response by stimulating the release of various cytokines, including interferon (IFN)γ, which in turn promotes the maturation of phagosomes; by upregulating adhesion molecule expression; activating neutrophils and enhancing macrophage and natural killer cell cytotoxicity (74, 75). TNFα also has essential functions in adaptive immune responses, including the expansion of γδ T cells, which are an important early source of IFNγ and can kill infected macrophages, and the recruitment of $CD4^+$ and $CD8^+$ T cells to the site of infection by inducing a variety of chemokines and enhancing the expression of adhesion molecules. Finally, TNFα plays a central role in the formation and maintenance of granulomas. Therefore, blockade of TNFα would be expected to severely hamper the immune response to intracellular bacteria in general and *M. tuberculosis* infection in particular.

Incubation of whole blood from tuberculin skin-test positive donors with infliximab and adalimumab at therapeutic drug concentrations resulted in a significant decrease in the proportion of activated ($CD69^+$) $CD4^+$ T cells responding to *M. tuberculosis* and a significant reduction in the antigen-induced secretion of IFNγ and IL-10 (77). Although etanercept also suppressed IL-10 production, it did not affect the proportion

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of tuberculosis-responsive T cells or their IFNγ synthesis. Similarly, infliximab and adalimumab inhibited the proliferation of PBMC from patients with previous or latent tuberculosis in response to stimulation with purified protein derivative (PPD) and other recall antigens, whereas etanercept showed a significant effect only at supra-therapeutic concentrations (78). Both infliximab and adalimumab decreased the fraction of $CD4^+$ T cells expressing tmTNFα, probably via internalization or shedding, whereas etanercept had no effect. While these observations provide a potential explanation for the differential risk of tuberculosis with etanercept compared to the mAbs, others found that etanercept and infliximab had very similar inhibitory effects on the secretion of IFNγ in whole blood from patients with active tuberculosis in response to stimulation with *M. tuberculosis*-specific antigens (79). The results from another in vitro study indicated that chronic exposure (16 days) of tetanus-toxoid-specific T cell clones to TNFα impaired their tetanus-specific proliferative response in a dose- and time-specific manner and suppressed their secretion of IL-2, IFNγ, lymphotoxin and TNFα (80). Conversely, cells pre-incubated with anti-TNFα mAb (infliximab) secreted higher levels of these cytokines and also of IL-10 compared to untreated cells. This suggests that neutralization of TNFα might actually have beneficial effects on antigen-specific T cell responses *in vivo*.

In patients with RA, SpA or CD who showed normal proliferative or IFNγ responses to the recall antigen PPD, 14 weeks of treatment with TNF antagonists left the PPD-specific proliferative response unaltered, but significantly reduced the number of PPD-specific IFNγ-producing cells (78). The decreases were similar after treatment with infliximab or etanercept and were independent of the underlying disease. Others also found that infliximab therapy profoundly suppressed antigen-specific IFNγ responses in patients who had not shown evidence of immunosuppression at baseline (76). Infliximab therapy in patients with AS was also associated with decreased frequencies of $CD4^+$ T cells producing IFNγ and TNFα in response to non-specific stimulation or stimulation with overlapping peptides of an AS-associated autoantigen compared to the placebo group (81). Interestingly, the same assays revealed upregulation of CD4 T cell responses in etanercept-treated AS patients compared to placebo (82).

Many RA and SpA patients show evidence of immunosuppression. Interestingly, and in contrast to the preceding results, treatment of such patients with etanercept or infliximab significantly enhanced the proliferation and IFNγ production of their PBMC stimulated with PPD, other recall antigens, or mitogens (80, 83-86). After a single infliximab infusion (either 1 or 10 mg/kg, the customary dose for RA patients being 3 mg/kg), the numbers of CD45RA-(memory) $CD4^+$ T cells, but not $CD8^+$ T cells, producing IFNγ or IL-4 were increased significantly, the rise being more pronounced for IFNγ-producing cells (87). Also, the number of peripheral CD45RA- T lymphocytes increased in both the $CD4^+$ and $CD8^+$ T cell subsets. This rise in the proportion of peripheral memory T cells, which are likely to include recall antigen-specific T cells, could explain the enhanced T cell response to recall antigens observed in other studies (87). The significance of these observations is that the data illustrates the multitude of pleiotropic immunologic actions of these agents. The blockade of a molecule as pleiotropic as TNF would therefore be expected to have significant clinical implications.

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As discussed previously, the immune system is incredibly diverse. Equally true is that TNF, including other cytokines, have an enormous and diverse number of roles as well within the immune system. Thus it is not surprising that treatment with Humira has broad implications for the immune response, including the risk of non-melanoma skin cancer. For example, as published earlier (88), to understand anti-cytokine therapy, one is required to have some understanding of the myriad roles of cytokines, chemokines, and their ligands on the immune response, as well as a thorough understanding of the various lymphoid subpopulations incriminated in autoimmunity, including not only CD4 cells, but, more importantly, T regulatory cells, B cells and a variety of other lineages. An extensive discussion of these concepts is beyond the scope of this review. Suffice it to say, it has been extensively studied in both humans and a variety of animal models (89-130). These discussions and citations are important because they evidence the Bradford-Hill criteria of comparison by analogy.

Tumor necrosis factor-α (TNF; cachexin or cachectin) is a member of a group of cytokines that stimulates the acute phase reaction of the immune system, part of our innate immune system. TNF-α is a pro-inflammatory cytokine. It induces apoptotic cell death and inflammation as well as inhibits tumorigenesis and viral replication. Tumorigenesis is the biology of tumor formation. TNF-α can be synthesized initially by activated macrophages and T cells as a transmembrane precursor protein (131-136). The cytoplasmic tail of this protein is then cleaved to release soluble TNF. The biological activity of TNF requires the aggregation of three TNF monomers to form trimeric TNF, which then acts by binding to one of the two types of receptors: TNFR1 or TNFR2 (137, 138). Both TNFR1 and TNFR2 are expressed on the surface of most mammalian cell types. Consequently, TNF-α has a broad spectrum of biological effects.

TNF-α also stimulates the release of the inflammatory cytokines (interleukin (IL) 1beta, IL-6, IL-8, and GM-CDF) and upregulates a series of critical chemokines (MCP-1, MIP-2, RANTES, and MIP-1α). It is also a potent activator of endothelial adhesion molecules (ICAM-1, VCAM-1, and E-selectin). These functions of TNF-α regulate initiation and perpetuation of important events associated with an inflammatory reaction (139, 140). Levels of TNF-α are elevated both locally and systemically in chronic inflammatory diseases such as RA, ankylosing spondylitis, psoriasis, and Crohn's disease suggesting that higher levels of TNF-α may directly contribute to tissue damage (141, 142).

Studies in animals have demonstrated the important role of TNF-α in protection against pathogens including *M. tuberculosis*, *Mycobacterium avium*, *M. bovis*, Bacillus Calmette–Guerin (BCG), *Aspergillus fumigatus*, *Histoplasma capsulatam*, *Toxoplasma gondii*, *Cryptococcus neoformans*, and *Candida albicans* (139, 143-146). Host defense against these organisms relies on sequestration within granulomas, which are comprised of a central core of macrophages, multinucleated giant cells, and necrotic debris surrounded by macrophages and lymphocytes (147). TNF-α helps to recruit these cells and is required for the continued maintenance of the granuloma structure (148, 149). In mice studies, when TNF-α has been neutralized, there was reactivation of latent TB and outbreak of disease as well as increased susceptibility to *Histoplasma*, *Listeria*, *Klebsiella*, and *Streptococcus* (148, 150-153). These data further highlight Bradford-Hill criteria, in

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particular criteria 5, 6, 7 and 8, including biologic gradient or dose-response relationship, biologic plausibility, coherence and experiment. It should, of course, be noted that not every study has found an increased risk of infection. Obviously all data is dependent on the nature of the host, the duration of therapy, the level of exposure and the nature of the underlying disease.

It should not be left unsaid that the role of TNF and its blockade in a variety of animal systems has been extensively studied and are, as expected, consistent with human data. This will not be reviewed in depth except to note that the relevant literature is peer reviewed and its data is consistent with the observation that the use of anti-TNF agents can increase the risk of non-melanoma skin cancer (139, 153-167). These data are consistent with a large variety of human immunobiology which reflects that treatment with anti-TNF will block multiple immune components, including T cells, dendritic cells, influence T regulatory cells, and a myriad of lymphoid populations (168-171). This fulfills the Bradford-Hill consistency criteria.

The use of Humira in psoriasis is well established in the medical literature. Although there is considerably more data on safety and toxicity of Humira in rheumatoid arthritis patients, it should be noted that the principles involved in the immunobiology and management of psoriasis are similar (172). There is considerable support for this statement in the medical literature and this again illustrates one of the principles of Bradford-Hill criteria, the criteria of analogy as well as specificity of the relationship. This literature includes the following (173-196).

Equally important to my opinions in this case was a review of unpublished, internal Abbott data (197). In another document entitled "Malignancies and Adalimumab: A White Paper," there is considerable, statistically significant, unpublished Abbott data that supports a causal connection between Humira and NMSC [ABT 00251790-00251866]. In this paper, which to my knowledge has not been published in this fashion, Abbott discusses Humira and malignancies. The internal clinical trial psoriasis data is consistent with the opinions and discussion herein. I will quote from the Abbott document: "The pathophysiology of psoriasis involves abnormal immune response and thus has been hypothesized to be associated with an increased risk of lymphoma and other cancers. Similar to the association of disease severity and malignancy risk in RA, an association is probable between psoriasis severity and the risk for malignancy (198, 199). Please note I have taken into account the data on the slight elevation of cancer in patients with psoriasis; this elevation is consistent with the increased risk of cancer in inflammatory conditions (198-201). Indeed, one would have anticipated that an agent such as Humira, that reduces psoriasis and therefore reduces inflammation, would have reduced the risk of skin cancer. Abbott's clinical trial data, which is discussed in the Abbott White paper, notes a slight elevated risk for overall cancer in psoriasis patients but this risk does not take into account the medications being used to treat this patient population. [White Paper Cite at 16-17]. The paper also noted that there is a probable association between severity of psoriasis and malignancy. But on the other hand, Abbott equally acknowledged that "immunosuppression may play a key role in the development of both SCC and BCC (Basel Cell Carcinoma), although the incidence of SCC may be more affected by immunosuppression than that of BCC." [White Paper at 9-10]. There is further discussion in the

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Abbott White paper regarding cancer risk and one important point reflects the individual variation, reflecting genetic differences between patients, illustrating the difficulties inherent in many epidemiologic studies. In other words, if there is biologic plausibility, then the risk factor will be at least in part determined by the specific person who takes Humira. In the White Paper, Abbott also compared the rates of various cancers for patients taking Humira to patients in the same clinical trials who were taking a control medication. The SIR for SCC was a statistically significant 3.63 [95% CI = 1.33 - 7.91]. *Id.* at p. 48. The paper concludes that "the SIRs for BCC and SCC were much higher in the adalimumab group than in the control group, including a statistically significant elevation in SCC among adalimumab patients (SIR 3.63, 95% CI 1.33 - 7.91). . . . No cases of BCC or SCC were diagnosed in the control group during the double-blind phases of these trials." The tables in the White Paper do not detail the duration of exposure of these patients. However, a slide presentation to the Safety Council in January of 2007 by a Dr. Jeff Kent contains exposure data. [ABT 03389923-03389963.] The slideshow provides the White Paper data but also the following information: "median exposure duration is 5.7 months for adalimumab-treated subjects." ABT 03389928. This slide show also noted that the rate of NMSC among Humira treated patients in its European controlled clinical trial data was a statistically significant (95% confidence interval) 8.8 (5.4, 14.4) per 1000 patient-years as compared to 2.3 (.6, 9.0) per 1000 patient-years for placebo patients. ABT03389958. Of this NMSC data, the rate of SCC in Humira treated clinical trial patients was also statistically significant at the 95% confidence interval: 2.8 (1.1, 6.6) per 1000 patient-years as opposed to 0 per 1000 patient years among control patients.

In addition to the clinical trial data, Abbott also looked at data from national registries which it acknowledged to be "1 of the best ways to assess drug performance in clinical practice." [White Paper at p. 36]. The British Society of Rheumatology Biologics Registry showed a IRR of 1.9 for all NMSCs and patients on Humira. For all anti-TNFs combined, the figure was 2.11. [White Paper Table 8, p. 53]. Additionally, in the January '07 Safety Council meeting, Abbott concluded that: "Melanoma and non-melanoma skin cancer rates are increased in patients treated with biologics."

Dr. Kent, who gave the Safety Council slide presentation mentioned earlier, stated the following in an email:

> Dominik's note is that he wants to "position" the skin finding. The skin finding is present and the positioning should be as such. Using the Wolfe data to bridge across compounds is fine, but they need to leave the meeting *knowing that our skin data demonstrates a finding*."

Email of 11/1/06 to Dr. Rebecca Hoffman. [ABT 01110557-01110565.] In another email dated 10/31/06, Dr. Kent stated the following: "to me the incidence of non melanoma skin cancer is elevated and should be communicated asf such." [ABT 01110560.]

This data from Abbott's clinical trials and national registries is consistent with other scientific literature in the public domain, with information from Abbott's post-marketing adverse event reporting.

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Additional evidence that I have considered from Abbott data is their "Risk Management Plan." [ABT 05587056-05587610.] On page 26 of this document, Abbott identifies "important identified risks" of using Humira as "[i]mportant AEs with adequate evidence of an association with adalimumab treatment…" [ABT 05587081.] Later in the document NMSC is described as an "identified risks." It appears that based on its own data, Abbott, too, considers NMSC to be an adverse event related to Humira treatment for which adequate evidence exists for a definitive association.

Equally compelling is that Abbott's data is also consistent with the reported data for other TNF inhibitors. For example, the "Risk" assessment reported in Table 5 of the White Paper for NMSC for all TNFs was a statistically significant 3.6 in one study, and a non-statistically significant 1.24 in another, presumably smaller study. [Table 5 at pg 29.] Similarly, the Remicade (infliximab) package insert shows 3 cases of NMSC (2 of which were SCC) in patients taking that drug vs. zero on placebo. [White Paper at p.33]. This data came from a 24 week trial. In another trial, which lasted only 10 weeks, one patient developed SCC and this development "was considered by the investigator to be reasonably related to the study agent." [White Paper at p. 33-34].

Enbrel (etanercept) was similar according to the White Paper. Twelve patients developed 13 cases of NMSC (8BCC cases and 5 SCC cases). Only one patient in the placebo arm developed SCC, although he/she had two "occurrences" of it. [White Paper at 34.] In sum, it also appears that there is consistency across the class of drugs with respect to this association. Thus, of course, further fulfills Bradford-Hill criteria for consistency.

The final section of this report will deal with specific observations on psoriasis and will illustrate that the risk factors already cited by Abbott are correct, i.e. there is an increased risk of non-melanoma skin cancer in patients treated with anti-TNF agents and particularly Humira. Before doing so, I want to emphasize the significant peer review literature that affirms the biologic and immunological implications of blocking TNF-α. Further, these papers illustrate not only the risk of skin cancer, but also are important for an understanding of the relative role of immunosuppression in the development of cancer, the role of viral infections in development of cutaneous and oral cancer, and especially the molecular basis of non-melanoma skin cancer, as they all relate directly to understanding how anti-TNF agents will predispose select individuals to this complication. These citations are fundamental as they all will place the field into the perspective of Bradford-Hill criteria regarding causation and particularly medical plausibility (21, 64, 202-226).

There are obvious questions regarding why specific patients develop skin cancer when treated with anti-TNF agents and others do not. This is readily explained by the genetic differences that exist in people. For example, there are 12 different psoriasis susceptibility loci that are differentially altered or regulated in psoriasis. These include: 6p21.3, 17q25, 4q, 1q21, 3q21, 19p13, 1p, 16q, 4q31-4q34, 18p11.23, 5q31.1-5q33.1, 20q13 (227). In fact, there are a number of psoriasis-related genes that have been identified in

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genome-wide associations and when one looks at those reported genes, they for the most part produce gene products that interact with the immune system. For example, psoriasis initiation is described in an initiation phase in which dendritic cells act on keratinocytes and release TNF and IL-23. In fact, when interaction takes place, activated NKT cells occur and they also alter the production of TNF. In fact, immune suppression and skin cancer development has been previously shown to undergo regulation by the same population of NKT cells (228). Finally, within the layers of the skin, there is a subpopulation known as Th17 cells and they likewise produce TNF, including other cytokines (172, 229-232). When one places this in the context of the cross talk that occurs between keratinocytes and the inflammatory reaction and the variability between the gene products and various SNPs, it is not surprising that there is considerable variation on susceptibility. Hence, one would not expect every epidemiology study to show associations. It would very much depend upon the population under study, the duration of exposure as well as individual variations. In this respect, it should be noted that a recent study of malignancies associated with TNF-α indicated that TNF inhibitors have a significantly increased risk of developing a non-melanoma skin cancer (1.45, 95% CI 1.15 to 1.76) (233). The latter study was based on a systematic review of prospective observational studies in usual clinical type settings. In fact, the inclusion criteria are important for this discussion: "In this report, we included all studies that reported data for malignancies associated with TNFi treatment that: (1) were a prospective observational registry set up for the assessment of outcomes in rheumatology; (2) included patients with RA, PsA or ankylosing spondylitis; (3) included patients receiving TNFi therapy. Only English language studies were included. Studies with less than 100 exposed patients were excluded. Retrospective studies were excluded to minimise heterogeneity. Administrative databases were also excluded as they do not capture disease-specific clinical data and were not set up prospectively with the purpose of analysing outcome data. Initially, titles and/or abstracts for all identified citations were reviewed independently by two of the authors (RH, CW) (first pass), followed by a second review stage of full-text publications using a recognised method of positive inclusion (RH, CW) (second pass) (234). Full details are provided online in the protocol. Disagreements regarding the inclusion of articles were resolved by discussion between all authors. Following the screening stages, one reviewer extracted data (CW). The data extraction was performed using a similar protocol to Sugiyama *et al.* (235). Data extracted included the study design, patient characteristics and malignancy (all-site, haematopoietic and skin) outcomes. A second reviewer (RH) checked the data extraction in order to ensure accuracy; any inconsistencies were discussed and resolved at this stage. The Newcastle–Ottawa quality assessment scale (236) was used by one reviewer (CW) to assess the quality of the included publications. This tool is designed specifically for non-randomised studies and avoids the reporting of summary scores, which have been shown to be unreliable and difficult to interpret (237)." Citation of this quotation is important as it helps place all of my earlier discussion in perspective.

This observation is recapitulated in a study of 23,458 patients exposed to Humira (175). In that study the SIR for non-melanomic skin cancer is shown in Figure 3 and is based on 184 events. Essentially, for non-melanoma skin cancer, patients with rheumatoid arthritis, psoriasis and Crohn's disease had SIRs with a 95% confidence interval greater than 1, indicating as per the authors, a higher number of observed cases than expected in the general population. Indeed, in psoriasis, the confidence intervals were 1.26 to 2.39.

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This observation of an increased risk of skin cancer is also confirmed in a study of rheumatoid arthritis involving 15,789 patients in which survival analysis, multi-variate Cox proportional analysis models were used for analysis. Essentially, the conclusion was that in this large national cohort, rheumatoid arthritis was associated with an increased risk for development of skin cancer, and amongst patients with rheumatoid arthritis use of Prednisone and TNF inhibitors were associated with increased risk of non-melanoma skin cancer (238). Interestingly, the latter is the first large case cohort study of the association between non-melanoma skin cancer, rheumatoid arthritis and immunosuppression, but the authors note that their data is in concert with current theories and they emphasize screening for skin cancer in patients with RA, but particularly those patients receiving immunosuppressive drugs.

A more recent study from the Veteran's Administration involving a cohort of 20,648 patients with rheumatoid arthritis is also in concert with my opinions and agrees with the data presented above. In this study, they advise rheumatologists to carefully screen patients who receive TNF inhibitors for pre-cancerous skin lesions and skin cancer. They emphasize that when cancers are considered individually, there is a trend of increased skin cancer risk across the studies (238-241).

The relationship between anti-TNF inhibitors like Humira and NMSC was recently recognized in a generally accepted, peer reviewed on line medical reference called UpToDate. UpToDate is a common website published by Wolters-Kluwer Health that updated this issue on May 13, 2013 through a process of peer review. Their summary is similar to the data I cite above and notes the following (242): "Evidence of an increased risk of non-melanoma skin cancer among patients treated with TNF inhibitors includes meta-analyses of data from registries, from prospective observational studies, and from randomized trials (203, 233, 239, 241). More limited studies have suggested an increased risk of malignant melanoma (233, 241, 243). The range of evidence for increased risk of non-melanoma skin cancer is demonstrated by the following: *In a systematic review and meta-analysis of data from four observational studies involving over 28,000 patients, the risk of non-melanoma skin cancer was significantly increased among patients exposed to TNF inhibitors compared with those who were not (relative risk [RR] 1.45, 95% CI 1.15-1.76) (233). The risk of non-melanoma skin cancer was significantly increased in patients treated with TNF inhibitors among a cohort of 20,648 patients with RA followed in the national administrative databases of the US Department of Veterans' Affairs, compared with patients who had received nonbiologic DMARDs (18.9 versus 12.7 per 1000 patient-years; hazard ratio [HR] 1.42, 95% CI 1.24-1.63 (239). *A meta-analysis of patient-level data from randomized trials of TNF inhibitor therapy, involving 15,418 patients, showed a significantly increased risk of non-melanoma skin cancer among patients receiving TNF inhibitors (RR 2.02, 95% CI 1.11-3.95) (203)."

I have not specifically cited case reports other than those included above, but there are also a number of case reports which illustrate that Humira is associated with non-melanoma skin cancer (193, 196).

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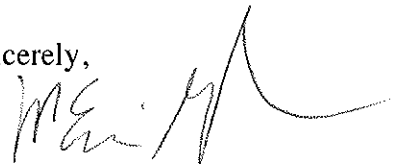
Each and every one of the Bradford-Hill criteria are fulfilled in the data cited above. In particular, I want to emphasize consistency of the data (in particular, the literature that is consistent for the immunological effects of blocking TNF), specificity of the data (the influence of anti-TNF-α on specific cancers), dose response and temporality (as cited above). Biologic plausibility, particularly based on the detailed mechanisms of action in relationship to immunosuppression, is also present and well understood by the medical community. There is coherence between the epidemiological data and the laboratory immunological features. In addition, there is considerable literature that reflects the analogy of other immune suppressed states, such as organ transplants, and the risk of non-melanoma skin cancer. There is also biologic plausibility based on the literature of immune suppression and development of skin cancer. There is also the Bradford-Hill criteria on experiment based on the animal experiments and including the ability to transfer susceptibility with immune cells that have been immunosuppressed. There is strength of the association based on both human and animal data and including the meta-analysis discussed above.

Potentially even more compelling is the clinical trial data that also achieves statistical significance both with respect to SIR's and rates. Although statistical significance is not always the ultimate arbiter on causal relationships, in this instance, in combination with the Bradford-Hill criteria outlined above, it paints a convincing picture of a causal relationship between Humira, NMSC, and more specifically, SCC.

In summary, use of Humira is causally associated with an increased risk of non-melanoma skin cancer and therefore can cause cancer in genetically susceptible individuals.

If you have any additional questions, please do not hesitate to contact me.

Sincerely,



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September 24, 2013

Andy Vickery
The Vickery Law Firm
10000 Memorial Drive, Suite 888
Houston, TX 77024-3412
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RE: Humira and Skin Cancer

Dear Mr. Vickery:

A total of $31125.00 has been billed for my work on Humira and skin cancer.

Sincerely,

M. Eric Gershwin, M.D., M.A.C.P., M.A.C.R.
Distinguished Professor of Medicine
The Jack and Donald Chia Professor of Medicine
Chief, Division of Rheumatology, Allergy and Clinical Immunology

CURRICULUM VITAE

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DATE AND PLACE OF BIRTH: January 19, 1946, New York, New York

MARITAL STATUS: Married, three children; wife D.V.M., Ph.D.: UC Vet School Faculty

COLLEGE: Syracuse University, Syracuse, New York
A.B., 1966 (summa cum laude), Phi Beta Kappa, Pi Mu Epsilon (mathematics)

MEDICAL SCHOOL: Stanford University, Stanford, California
M.D., 1971 (Alpha Omega Alpha)

GRADUATE SCHOOL: Centre for Astrophysics and Supercomputing, Melbourne, Australia
M.S., 2002 (Astronomy and Astrophysics)

HONORARY DEGREES AND SPECIAL AWARDS:
1. Doctor of Philosophy, Honoris Causa, University of Athens. 2009. Awarded by the Rector for a lifetime contribution in immunology and medicine, the highest honor bestowed by the University of Athens.
2. AESKU Prize in Autoimmunity: For lifetime contribution in immunology, 2008.
3. Fellow, American Association for the Advancement of Science, 2012.
4. Vasco Da Gama Prize (Portugal) for a lifetime of deep explorations in immunology to benefit mankind, 2013.

PROFESSIONAL EXPERIENCE:

2003-present	Distinguished Professor of Medicine, Division of Rheumatology/Allergy and Clinical Immunology, University of California, Davis, California
1994-present	The Jack and Donald Chia Professor of Medicine, Division of Rheumatology/Allergy and Clinical Immunology, University of California, Davis, California
1989-2001	Chairperson, Graduate Group in Immunology, University of California, Davis, California
1985-1986	Guggenheim Fellowship and Visiting Scientist, Walter and Eliza Hall Institute of Medical Research, Melbourne, Australia.
1982-present	Chief, Division of Rheumatology/Allergy and Clinical Immunology, University of California School of Medicine, Davis, California.
1981-present	Professor of Medicine (Rheumatology and Allergy), University of California School of Medicine, Davis, California.
1977-present	Director, Allergy-Clinical Immunology Program, University of California School of Medicine, Davis, California.

1977-1981	Associate Professor of Medicine (Rheumatology and Allergy), University of California School of Medicine, Davis, California.
1976-1979	Director, Special Immunology Diagnostic Laboratory, University of California School of Medicine, Davis, California.
1975-1977	Assistant Professor of Medicine (Rheumatology and Allergy), University of California School of Medicine, Davis, California.
1973-1975	Clinical Associate, Immunology, National Institutes of Health, Bethesda, Maryland.
1971-1973	Internship, Residency: Tufts-New England Medical Center, Boston, Massachusetts.
1970	January-May: Smith, Kline and French Fellowship in Tropical Medicine, Memorial Christian Hospital, Sialkot, West Pakistan.
1967	Summer: Department of Pharmacology, University of Switzerland. Dr. Peter Waser: Uptake and distribution of drugs using autoradiography.
1966-1971	Clinical pharmacology research - Dr. N. Ty Smith, Stanford Medical School.
1965	Summer - Institute of Arctic Biology, University of Alaska, College of Alaska. Drs. Peter Morrison and Larry Irving: Comparative electrophoretic and immunodiffusion patterns of arctic rodents.

LICENSING AND CERTIFICATION:

Certified:	American Board of Internal Medicine - 1974 American Board of Internal Medicine, subspecialty of Rheumatology - 1978 American Board of Allergy and Clinical Immunology - 1980
Licensed:	California (active) Maryland (inactive) Massachusetts (inactive) New York (inactive)

PATENTS (INVENTIONS):

"Recombinant Autoantigen of Primary Biliary Cirrhosis" with Walter and Eliza Hall Institute for Medical Research and the Commonwealth of Australia. Patent Act 1952 (Davies and Collison, Patent Attorneys) 1987.

"Use of Recombinant Cloned Antigens as Diagnostic Reagents". Patent Act 1952 (Davies and Collison, Patent Attorneys), 1988.

"Primary Biliary Cirrhosis Autoantigens" with AMRAD Corporation Ltd. Serial No. 25919, 1990.

"Nonmethylene Interrupted Fatty Acids As Immuno-Modulators", University of California, patent pending 93-125-1 (United States; Mexico; Europe), 1993.

"Recombinant Fusion Protein Comprising PDC-E2, and OGDC-E2 and Uses Thereof" (U.S. Patent No. 6,111,071, Issued: August 29, 2000).

"Xenomice-derived Human Monoclonal Antibodies" (U.S. Patent ABX-UCD1 PCT, pending), filed by Fish and Neave, April 2002.

"Antibodies Against Autoantigens of Primary Biliary Cirrhosis and Methods of Making and Using Them" (U.S. Patent 60/279,052; 60/323,920; US02/09694), filed by OTT, University of California, 2001/2002.

"Autoantibodies and Primary Biliary Cirrhosis" (European Patent #02723662.9-2108 PCT/US0209694), filed by OTT, University of California, accepted August 8, 2003.

"Identification of *Novosphingobium Aromaticivorans* and Primary Biliary Cirrhosis" (U.S. Patent pending), filed by University of California, August 2003.

"Discovery of the Microorganism That Causes the Human Autoimmune Disease, Primary Biliary Cirrhosis" (U.S. Patent No. 10/893,608), filed by University of California, July 15, 2004.

HONORS, AWARDS:

Phi Beta Kappa: Syracuse University, 1965
Mary Marshall Award: Syracuse University, 1966
Pi Mu Epsilon (Mathematics): Syracuse University, 1966
Witco Chemistry Award in Organic Chemistry, Syracuse University: 1964, 1965, 1966
Stanford Award for Outstanding Student Research, 1968
Association of American Medical College Recognition in Tropical Medicine: 1970
Robert Shelton Alumni Scholar Award (for outstanding graduating medical student), Stanford University School of Medicine: 1971
Dermatology Prize, Stanford University: 1971
Alpha Omega Alpha: Stanford University, 1971
Guggenheim Fellowship, 1986
Distinguished Medal: Japanese Society of Hepatology, 1988
Professorial Award: Kagawa University, 1998
Alfred Cahen Memorial Lecturer, Case Western Reserve University, 2003
Best Doctors in America, 2001-present, each and every year
Life Sciences: Top 1% of all quoted researchers in medical sciences, 2005
Distinguished Medal, University of Milan, 2006
Henry Kunkel Society, 2006
Honorary Professor, Immunology, Shanghai University, May 2007-April 2010
AESKU Prize for Lifetime Contribution in Autoimmunity, September 2008
Doctor of Philosophy, Honoris Causa, University of Athens, 2009.
The Carbone Visiting Professor, University of California at San Francisco, 2009.
Master, American College of Physicians, 2009
Fellow, American Association for the Advancement of Science, 2012.

Travel Awards:

Eleventh Leukocyte Culture Conference, Tucson, Arizona: 1976; International Congress of Immunology, Sydney, Australia, 1977; American Association of Immunologists, 1977; Twelfth Leukocyte Culture Conference Beersheba, Israel, 1978; International Congress on Immunodeficient Animals, Lausanne, 1982; International Congress on Animal Models, Kyoto, 1985; International Congress on Mucosal Immunity, Berlin, 1991.
Research Career Development Award (NIAID): 1977-1982.
University of California Faculty Research Award, 1979, 1985.
Senior Investigator, American Rheumatism Association, 1982-1987.
Fogarty Senior International Fellowship, 1985.
John Simon Guggenheim Memorial Fellowship, 1985-1986.
Joan Oettinger Memorial Award, 1988.
Amrad Fellow, Melbourne, Australia, 1990.

MEMBERSHIPS:

American Association of Physicians
American Academy of Allergy and Immunology, Fellow
American Association of Immunologists
American Association for the Study of Liver Diseases
American College of Physicians, Fellow
American College of Rheumatology, Fellow
American Society of Clinical Investigation
Transplantation Society

Western Society for Clinical Research
Western Association of Physicians

PUBLIC SERVICE:

Reviewer, VA Career Development Awards, 1976-present.
Medical-Scientific Director, American Lupus Society, Sacramento Valley Chapter, 1977-1982.
Member, Medical-Scientific Committee, National Foundation for Ileitis and Colitis, Sacramento Valley Chapter, 1977-1980.
Immunogenetics Council Member End Stage Renal Disease Network, 1977-1985.
Nominating Committee, Comparative Immunology Division, 1977-1981.
Consultant, World Health Organization Genetic Control of Autoimmunity, Michigan, Wisconsin, 1978.
American Rheumatism Review Subcommittee, 1979-1981.
American Academy of Allergy Primer Group, 1980.
Council Member, Immunopharmacology Division of American Society of Pharmacology and Experimental Therapeutics, 1980-1983.
Immunology Study Section NIH, 1980, 1982.
Ad Hoc Reviewer National Science Foundation, 1979-present.
Consultant (Grants), Canadian Rheumatism Society, 1982-present.
Consultant, Kroc Foundation, 1980-1984.
Treasurer, International Society of Developmental and Comparative Immunology, 1980-1984.
Chairperson, Division of Comparative Immunology of the American Society of Zoologists, 1983-1987.
Council Member, American Rheumatism Association (Western Division), 1984-1986.
Immunology Subcommittee Western Society for Clinical Research, 1985.
Council Member, Myasthenia Gravis Foundation, 1984-1986.
Laboratory Refinement Committee, American Academy of Allergy and Clinical Immunology, 1985-1988.
State of California Committee on Arthritis Manpower and Resources, 1985-1987.
Vice President, American Rheumatism Association (Western Division), 1986-1987.
President; American Rheumatism Association (Western Division), 1987-1988.
Council Member, Western Society for Clinical Investigation, 1987-1990.
Council Member, Professional Information; American Academy of Allergy and Clinical Immunology, 1988-1990.
Board of Directors Member: American Rheumatism Association, 1988-1991.
Special Reviewer, National Research Council, National Academy of Sciences, Washington, DC, 1988.
Advisor, United States Food and Drug Administration (Nutrition and Immunity), 1991.
Council Member, Western Association of Physicians, 1992-present.
Member, National Institutes of Health, General Medicine Study Section A, 1990-1992.
Chairperson, National Institutes of Health, General Medicine Study Section A, 1992-1994.
Reviewer, Austrian Society for Allergy and Immunology, 1993-present
Reviewer, Thrasher Research Fund, 1993; 1996-present.
Consultant, California Environmental Protection Agency, Immunotoxicology Work Group (OEHHA, Cal/EPA), 1994-present.
National Institutes of Health Reviewers Reserve (NRR), 1994-present.
American Liaison, 4th International Conference on Systemic Lupus Erythematosus, 1994-1995.
Reviewer for John Simon Guggenheim Memorial Foundation Fellowships in Medicine, 1996-present.
Special Reviewer: University of Tel Aviv Sackler Faculty of Medicine, 1996-1998

Chair, American Liver Foundation Committee on Primary Biliary Cirrhosis, 1997-present.
External Advisor: University of Western Australia (Immunology), 1998.
External Advisor: Monash University Research Grants and Ethics Branch, Clayton, Australia, 1998.
Advisory Board, Liver Unit, Mt. Sinai Medical Center, New York, 1998-present.
Advisory Board, Physicians' Desk Reference, 1999-present.
Consultant, The Wellcome Trust, 2001-present
Member, Allergy and Immunology Scientific Committee of the California Medical Association's Council of Scientific Affairs, 2001-2005
Consultant, Federal Trade Commission, U.S. Government, 2002
Member, Scientific Advisory Board, American Autoimmune Diseases Association, 2003-present
Advisor, The Netherlands Organisation for Health Research and Development (ZonMw), 2003
Member, Academic Advisory Board of UC Davis CONNECT, 2003-present
Reviewer, United States-Israel Binational Science Foundation, 2002, 2003, 2004
Reviewer, Medical Research Council of the United Kingdom, 2002-2004
Consultant, Life Sciences Research Office (LSRU) and Center for Devices and Radiological Health, FDA (CDRH) Immunotoxicology, 2003-2004.
Reviewer, American Liver Foundation, 2004-present
Reviewer, Doris Duke Foundation, 2004-present
Reviewer, Austrian Science Foundation, 2004-05
Reviewer, French Science Foundation, 2005
Reviewer, University Grants Committee, Research Grants Council of Hong Kong, 2005
Consultant and Reviewer, Medical University of Graz, Austria, Ph.D. Program, 2006
External Reviewer for National Institute for Occupational Safety and Health (NIOSH), 2008
Reviewer, Israel Science Foundation, 2008-present
Reviewer, Swish National Science Foundation, 2009-present
Reviewer, National Library of Medicine, Genetics, 2010
External Reviewer, Islandic Center for Research, Laugavegi 13, 101 Reykjavik, Iceland, 2010
Reviewer, U.S. Army Medical Research and Material Command (USAMRMC), 2011
Member, Political Action Committee, American College of Rheumatology, 2010-present
Organizing Committee, International Sjogren's Congress, 2011

JOURNAL EDITOR:

Editor-in-Chief, Clinical Reviews in Allergy, 1983-present
Co-Editor, Allergologia et Immunopathologia, 1986-1998
Editor-in-Chief, Healthline-Allergies & Asthma, 1990-2000
Co-Editor, Reviews in Autoimmunity, 2001-present
Editor-in-Chief, Developmental Immunology, 2003-2006
Co-Editor-in-Chief, Autoimmunity Reviews, 2005-present
Editor-in-Chief, Journal of Autoimmunity, 2006-present

ASSOCIATE EDITOR:

Developmental and Comparative Immunology, 1986-1989
International Archives of Allergy and Immunology, 1992-1998
Journal of Autoimmunity, 1996-2006; currently Editor-in-Chief
Journal of Medicinal Foods, 2001-present
Experimental Biology and Medicine 2002-2005
Developmental Immunology, 2002-present

EDITORIAL BOARD SERVICE:

Immunopharmacology, 1977-1990
African Journal of Immunology, 1979-1984
Western Journal of Medicine, 1983-1990
Allergologia et Immunopathologia, 1985-present
American Zoologist, 1986-1990
Modern Medicine, 1988-present
Human Antibodies and Hybridomas, 1989-present
Current Medical Literature - Rheumatology, 1990-1992
Journal of Allergy and Investigative Immunology, 1991-present
Journal of Clinical Immunology, 1992-present
Seminars in Clinical Immunology, 1995-present
Turkish Journal of Immunology, 1996-present
Cellular Immunology, 1996-present
The Guide: A Time-Saving Summary of Clinical Guidelines, 1996-present
Clinical Therapeutics, 1997-present
International Medicine (Russia), 1997-present
PDR (Physician's Desk Reference) Advisory Board, 1998-present
inScight (Science Magazine), 1998-present
Seminars in Liver Disease, 1999-2002
Society for Experimental Biology and Medicine, 2001-2004
Clinical and Experimental Medicine, 2001-present
Journal of Traditional Medicine, 2002-present
Autoimmunity 2003-present
Seminars in Liver Disease, 2005
Gastroenterology, 2006-present
Journal of Gastroenterology, 2007-2009
Archives of Medical Science, 2007-present
Gerontology, 2007-present
World Journal of Gastroenterology, 2008-present
Chinese Medicine, 2008-present
Journal of Gastroenterology, 2008-2009
Hepatology Research, 2009-present
Liver Disease Review Letters, 2009-present
Seminars in Immunopathology 2010-present
Mediterranean Journal of Nutrition and Metabolism, 2010-present

OCCASIONAL REVIEWER:

American Family Physician
American Journal of Clinical Nutrition
American Journal of Enology and Viticulture
American Journal of Medicine
American Journal of Pathology
American Journal of Reproductive Immunology
Annals of Internal Medicine
Applied Genomics and Proteomics
Archives of Internal Medicine
Arthritis and Rheumatism
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Biochimica et Biophysica Acta
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Journal of American Medical Association
Journal of Biomedical Science
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Journal of Clinical Epidemiology
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Journal of Neuroimmunology
Journal of Nutrition
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Proceedings of the Society for Experimental Biology and Medicine
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Science
Science of the Total Environment
Southern Medical Journal
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BOOKS AND MONOGRAPHS

1. 1978 Gershwin, M.E. and E. Cooper (Eds.). Animal Models of Comparative and Developmental Aspects of Immunity and Disease. Pergamon Press, New York, 396 pp.

2. 1979 Gershwin, M.E. and S. Nagy (Eds.). Evaluation and Management of Allergic and Asthmatic Diseases. Grune and Stratton, New York, 287 pp.

3. 1981 Gershwin, M.E. (Ed.). Bronchial Asthma: Principles of Diagnosis and Management. Grune and Stratton, New York, 450 pp.

4. 1981 Gershwin, M.E. and B. Merchant (Eds.). Immunologic Defects of Laboratory Animals. Plenum Press, New York, 895 pp. (2 volumes).

5. 1982 Ruben, L. and M.E. Gershwin (Eds.). The Biologic and Evolutionary Significance of Immune Regulation. Marcel Dekker Press, New York, 400 pp.

6. 1983 Gershwin, M.E. and D.L. Robbins (Eds.). Musculoskeletal Diseases of Children. Grune and Stratton, New York, 800 pp.

7. 1984 Gershwin, M.E. Asma Broncquica, Diagnostico E. Tratemento, Roca Press, Inc., Sao Paulo, Brazil, 453 pp.

8. 1985 Gershwin, M.E., Beach, R. and Hurley, L.S. Nutrition and Immunity, Academic Press, 405 pp., New York.

9. 1985 Leek, J.C., Gershwin, M.E. and Fowler, W. (Eds.). Physical Medicine and Rehabilitation of Musculoskeletal Diseases. Grune and Stratton, Inc., Orlando, FL, 546 pp.

10. 1986 Gershwin, M.E. (Ed.). Bronchial Asthma: Principles of Diagnosis and Treatment. Grune and Stratton, Inc., 629 pp.

11. 1986 Gershwin, M.E. and Klingelhofer, E. Asthma: Stop Suffering, Start Living, Addison-Wesley, Inc., 221 pp.

12. 1989 Gershwin, M.E. and Klingelhofer, E. Conquering Your Child's Allergies, Addison-Wesley, Inc., 250 pp., New York.

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37 2003 Gershwin, M.E., J.M. Vierling, M.P. Manns (eds). Liver Immunology. Hanley and Belfus, Inc., Philadelphia, PA, 498 pp.

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39 2004 Gershwin, M.E., P. Nestel and C.L. Keen (eds.). Handbook of Nutrition and Immunity. Humana Press, Totowa, NJ, pages 1-365.

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41 2004 Gershwin, M.E. and E.L. Klingelhofer. Asthma: Stop Suffering, Start Living. Chinese translation and modification. Bardon-Chinese Media Agency, Cite Publishing Ltd., Taipei, Taiwan, 427 pages.

42 2004 Gershwin, M.E. and Y. Shoenfeld. Organ Specific Immunopathology. Clinical and Developmental Immunology 11(3/4):189-305.

43 2004 Naguwa, S.M. and M.E. Gershwin, (eds). Allergy and Immunology Secrets. CekpetbI Publishers, Russian edition of #44 below, pages 319.

44 2005 Gershwin, M.E. and S.M. Naguwa. Allergy and Immunology Secrets. Second edition. Elsevier Mosby Publisher, Philadelphia, pages 1-340.

45 2005 Gershwin, M.E. and Y. Shoenfeld. Autoimmunity: Concepts and diagnosis at the cutting edge. The New York Academy of Sciences, New York, NY.

46 2005 Shoenfeld, Y. and M.E. Gershwin (eds). Autoimmune diseases and treatment: Organ-specific and systemic disorders. Annals of the New York Academy of Sciences, New York, Volume 151, pages 1-815.

47 2005 Gershwin, M.E. (ed). Intravenous immunoglobulin: New indications and mechanisms of action. Clinical Reviews in Allergy and Immunology. Humana Press 29:165-350.

48 2006 Gershwin, M.E. and T.E. Albertson (eds). Bronchial Asthma: A Guide for Practical Understanding and Treatment, 5th edition. Humana Press, Inc., Totowa, New Jersey, 405 pages.

49 2006 Gershwin, M.E. and S.M. Naguwa (eds). Alergia e Immunologia Secretos. Second edition. Elsevier Mosby Publisher, Madrid, 384 pages. (Spanish translation of #44 above).

50 2006 Gershwin, M.E. and S.M. Naguwa (eds). Allergy and Immunology Secrets. Second edition. Medical Sciences International, 352 pages. (Japanese translation of #44 above).

51 2007 Shoenfeld, Y., M.E. Gershwin and P.L. Meroni (eds). Autoantibodies. Second edition. Elsevier, B.W. Publisher, 838 pages.

52 2007 Shoenfeld, Y. and M.E. Gershwin. Autoimmunity, Part C: The Mosaic of Autoimmunity. Foreword. Annals of the New York Academy of Sciences Vol. 1107.

53 2007 Shoenfeld, Y and M.E. Gershwin (eds). Autoimmunity, Part D. Autoimmune Disease, *Annus Mirabilis*. Annals of the New York Academy of Sciences, Blackwell Publishing, Boston, vol. 1108, 612 pages.

54 2007 Gershwin, M.E. and Y. Shoenfeld. Autoimmunity, Part A: Basic Principles and New Diagnostic Tools. Foreword. Annals of the New York Academy of Sciences Vol. 1109.

55 2007 Gershwin, M.E. and Y. Shoenfeld. Autoimmunity, Part B: Novel Applications of Basic Research. Foreword. Annals of the New York Academy of Sciences Vol. 1110.

56 2007 Gershwin, M.E., J.M. Vierling and M.P. Manns (eds). Liver Immunology: Principles and Practice. Humana Press, Totowa, NJ, 486 pp.

57 2008 Shoenfeld, Y., R. Cervera and M.E. Gershwin (eds). Diagnostic Criteria in Autoimmune Diseases. Springer Verlag, New York, NY 593 pp.

58 2009 Shoenfeld, Y. and M.E. Gershwin (eds). Cutting Edge Autoimmunology. Elsevier Press, Amsterdam, volume 32, 149-266 pp.

59 2009 Shoenfeld, Y. and M.E. Gershwin (eds). Contemporary Challenges in Autoimmunity. Annals of the New York Academy of Sciences, Blackwell Publishing, Boston, Volume 1173, pages 886.

60 2010 Gershwin, M.E. and M.R.C. Greenwood (eds). Foods for Health in the 21st Century: A Roadmap for the Future. Annals of the New York Academy of Sciences, Volume 1190, pages 1-192.

61 2010 Shoenfeld, Y., P. Youinou and M.E. Gershwin (eds). The Environment, Geoepidemiology and Autoimmune Diseases. Elsevier Publishing. Volumes 34/3 of Journal of Autoimmunity and Volumes 9/5 of Autoimmunity Reviews, pages J163-J338 and A247-A405.

62 2010 Gershwin, M.E., A.W. Lohse, M.P. Manns and D. Vergani (eds). Immunology and Liver Disease (Falk Workshop 2009). Falk Liver Conference, October 15 and 16, 2009, Hannover. Karger, pages 1-154.

63 2011 Gershwin, M.E. and T.E. Albertson (eds). Bronchial Asthma: A Guide for Practical Understanding and Treatment, Sixth Edition, Springer, New York, 436 pages.

64 2011 Shoenfeld, Y., M.E. Gershwin and P.L. Meroni (eds). Autoantibodies, Elsevier (Chinese).

65 2012 Shoenfeld, Y., A. Tincani and M.E. Gershwin (eds). Gender, Sex Hormones, Pregnancy and Autoimmunity. Elsevier, The Netherlands, pages J71-J282 and A377-A544.

EXPERIMENTAL PAPERS

1 1967 Gershwin, M.E. and N.T. Smith. Mode of action of hydralazine on guinea pig atria. Archives Internationales de Pharmacodynamie et de Therapie 170:108-116.

2 1968 Smith, N.T., M.E. Gershwin and E.J. Hurley. Hemodynamic effects of ouabain on the surgically denervated, autotransplanted dog heart. Archives Internationales de Pharmacodynamie et de Therapie 173:95-114.

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